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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/724,965	LONBERG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 57,59-61,64,66-68,71 and 76-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57,59-61,64,66-68,71 is/are rejected.
- 7) ☒ Claim(s) 76-80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's amendment and response received on 1/26/04 has been entered. The copies of originally filed pages 136-140 of the specification have also been received. Claims 58, 62-63, 65, 69-70, and 72-75 have been canceled, and new claims 76-80 have been added. Claims 57, 59-61, 64, 66-68, 71, and 76-80 are pending and under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

#### ***Priority***

The applicant has amended the specification to change the effective filing date of the application. The office acknowledges that the effective filing date of the instant application is October 10, 1995, based on the filing date of parent application 08/544,404.

#### ***Double Patenting***

The rejection of previously pending claims 57-58, 62-65, and 69-73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-3 of U.S. Patent No. 5,625,126 (4/29/97), hereafter referred to as the '126 patent, is maintained over

Art Unit: 1632

pending claims 57, 64, and 71. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant rejection for reasons of record as discussed in detail below.

The applicant argues that the claims have been amended to recite that the transgenic mouse comprises a human kappa light chain transgene "containing" five human light chain Vk segments. The applicant states that the mouse of amended claim 57 only possesses five human light chain Vk segments, and argues that the '126 patent does not disclose or suggest making a mouse with 5 Vk segments. In response, the word "containing" is open claim language and does not limit the number of Vk segments to 5. As such, claim 57 reads on transgenic mice with 5 or more Vk segments. As discussed in the previous office action, the specification of the '126 patent clearly teaches human kappa light chain transgenes which comprise a plurality of human light chain V genes, a plurality of light chain J genes, and a human light chain C gene ('126 specification, columns 15-17 and columns 57-60). According to the specification of the '126 patent, the number of variable genes can be 2, 4, or at least about 10 V segments. Thus, while the office agrees that the '126 patent does not specifically teach a kappa light chain transgene consisting of 5 Vk segments, the instant claims are not so limited as the language "containing" is broad and encompasses more than 5 Vk segments. Thus, as the transgenic mice recited in claims 2-3 of the '126 patent encompass more than 5 Vk segments, and the instant claims are broad and not limited to only 5 Vk segments, claims 2-3 render obvious the transgenic non-human animals of instant claims 57, 64, and 71.

Art Unit: 1632

The rejection of previously pending claims 57-58, 62-65, and 69-73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 5,789,650 (8/4/98), hereafter referred to as the '650 patent is maintained over pending claims 57, 64, and 71. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant rejection for reasons of record as discussed in detail below.

The applicant argues that the claims have been amended to recite that the transgenic mouse comprises a human kappa light chain transgene "containing" five human light chain Vk segments. The applicant states that the mouse of amended claim 57 only possesses five human light chain Vk segments, and argues that the '650 patent does not disclose or suggest making a mouse with 5 Vk segments. As noted above, the word "containing" is open claim language and does not limit the number of Vk segments to 5. As such, claim 57 reads on transgenic mice with 5 or more Vk segments. As discussed in the previous office action, the specification of the '650 patent clearly teaches human kappa light chain transgenes which comprise a plurality of human light chain V genes, a plurality of light chain J genes, and a human light chain C gene ('650 specification, columns 21-25, and 41-42). According to the specification of the '650 patent, the number of variable genes can be 2, 4, or at least about 10 V segments. Thus, while the office agrees that the '650 patent does not specifically teach a kappa light chain transgene consisting of 5 Vk segments, the instant claims are not so limited as the language "containing" is broad and encompasses more than 5 Vk segments. Thus, as the transgenic mice recited in claim 5 of the '650 patent encompass more than 5 Vk segments, and the instant claims are broad and not

Art Unit: 1632

limited to only 5 Vk segments, claim 5 renders obvious the transgenic non-human animals of instant claims 57, 64, and 71.

The rejection of claims 57-58, 61-65, and 68-73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,877,397 (3/2/99), hereafter referred to as the '397 patent, is maintained over pending claims 57, 64, and 71. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant rejection for reasons of record as discussed in detail below.

The applicant argues that the claims have been amended to recite that the transgenic mouse comprises a human kappa light chain transgene "containing" five human light chain Vk segments. The applicant states that the mouse of amended claim 57 only possesses five human light chain Vk segments, and argues that the '397 patent does not disclose or suggest making a mouse with 5 Vk segments. As noted above, the word "containing" is open claim language and does not limit the number of Vk segments to 5. As such, claim 57 reads on transgenic mice with 5 or more Vk segments. As discussed in the previous office action, the specification of the '397 patent clearly teaches human kappa light chain transgenes which comprise a plurality of human light chain V genes, a plurality of light chain J genes, and a human light chain C gene ('397 specification, columns 21-25, and 41-42). According to the specification of the '397 patent, the number of variable genes can be 2, 4, or at least about 10 V segments. Thus, while the office agrees that the '397 patent does not specifically teach a kappa light chain transgene consisting of 5 Vk segments, the instant claims are not so limited as the language "containing" is broad and

Art Unit: 1632

encompasses more than 5 Vk segments. Thus, as the transgenic mice recited in claims 1-10 of the '397 patent encompass more than 5 Vk segments, and the instant claims are broad and not limited to only 5 Vk segments, claims 1-10 render obvious the transgenic non-human animals of instant claims 57, 64, and 71.

***Claim Rejections - 35 USC 112***

The rejection of previously pending claims 57-62, 64-69, and 71-75 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn in view of applicant's amendments to the claims and/ or cancellation of the claims.

The rejection of claims 64-71 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements is withdrawn in view of applicant's amendment and or cancellation of the claims.

Applicant's amendment to the specification which changes the effective filing date of the application to 10/10/95, and applicant's amendment to the claims have resulted in the following new grounds of rejection.

Art Unit: 1632

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 57, 59-61, 64, 66-68, and 71 are newly rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,150,584 (11/21/00), hereafter referred to as Kucherlapati et al..

The applicant has amended the priority of the application so that the effective filing date is now 10/10/95. Therefore, Kucherlapati et al. now qualifies as prior art based on the effective filing date of Kucherlapati et al. which is at least 4/27/95. Further, as noted above, the language “containing five human light chain Vk segments” is not limited to only 5 Vk segments, and encompasses more than 5 Vk gene segments.

The applicant now claims a transgenic mouse which comprises a transgene containing 5 human light chain kappa Vk segments, a plurality of Jk segments, and a Ck segment operably



Art Unit: 1632

linked to transcription regulatory sequences, and which undergoes rearrangement in B cells to produce a repertoire of rearranged human kappa light chain transgenes and polypeptides. The applicant further claims said mice which have an inactivated endogenous mouse kappa light chain locus or which have a human heavy chain transgene. The applicant also claims said mice wherein the transgene comprises the human 3' kappa enhancer segment.

Kucherlapati et al. teaches transgenic mice with an inactivated endogenous kappa light chain locus which comprises an 880 kb YAC which comprises 650 kb of the human kappa light chain proximal variable region which contains more than 5 Vk segments, the entire Jk region, and the Ck segment with its flanking sequences through the Kde, which appears to be greater than 12 kb from the Ck gene ( Kucherlapati et al., column 4, Figure 2, and claims 1-7). Please note that the human 3' kappa enhancer is located 12 kb downstream from the Ck gene and is naturally located within a BamHI fragment. Kucherlapati et al. also teaches wherein the transgenic mouse further includes a human heavy chain transgene and wherein the mouse comprises an inactivated endogenous kappa light chain locus (Kucherlapati et al., claims 1-7). Thus, by teaching all the elements of the claims as written, Kucherlapati et al. anticipates the invention as claimed.

Claims 76-80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1632

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

**ANNE M. WEHBE' PH.D**  
**PRIMARY EXAMINER**

